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blank solution. 6 injections of the working standard III were made. The system suitability injections were then tested to verify that they met the system suitability criteria as shown in Table 2.

TABLE 5

System Suitability Criteria	
Parameter	Acceptance Criteria
Resolution between Codeinone and 14-Hydroxycodeinone	NLT 8
Resolution between 14-Hydroxycodeinone and Oxycodone	NLT 2
Tailing factor for Oxycodone	0.7-2.0
Relative retention times for Codeinone based on Oxycodone	Approx. 0.44
Relative retention times for 14-Hydroxycodeinone based on Oxycodone	Approx. 0.85
% RSD of 6 system suitability injections for Codeinone and 14-Hydroxycodeinone	NMT 20%

The expected retention times were as follows:

Components	Expected Retention Times
Codeinone	14 ± 2 min
14-Hydroxycodeinone	27 ± 4 min
Oxycodone	32 ± 6 min

I. Injection Procedure

Once the column was equilibrated, the sample and standard solutions were injected according to the following sequence of Table 3:

TABLE 6

Blank (diluent)	1 injection
Resolution solution	1 injection
Working Standard III	6 injections for RSD, last 2 injections for calibration
Blank (diluent)	2 injections
Unspiked Oxycodone solution	2 injections
Sample 1 Prep# 1	2 injections
Working Standard III	2 injections
Sample 1 Prep# 2	2 injections
Sample 2 Prep# 1	2 injections
Sample 2 Prep# 2	2 injections
Working Standard III	2 injections
Sample 3, Prep# 1	2 injections
Sample 3, Prep# 2	2 injections
Working Standard III	2 injections

The Codeinone and 14-Hydroxycodeinone peaks were identified using the relative retention times as discussed above.

Calculations

The responses of Codeinone and 14-Hydroxycodeinone peaks were measured and recorded. The content of Codeinone and 14-Hydroxycodeinone was calculated in ppm using the following equation:

$$ppm = \frac{Rs \times Wstd}{Rstd \times Ws} \times \frac{1}{100} \times \frac{1}{50} \times \frac{1}{10} \times \frac{10}{1} \times \frac{1,000,000}{1}$$

$$ppm = \frac{Rs \times Wstd \times 200}{Rstd \times Ws}$$

Where:

ppm=Parts per millions of codeinone or 14-Hydroxycodeinone in Oxycodone HCl

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Rs=Response of Codeinone or 14-Hydroxycodeinone in Sample Solution.

Rstd=Response of Codeinone or 14-Hydroxycodeinone in Standard Solution minus the response of unspiked standard

Wstd=Weight of Standard, corrected for purity, mg

Ws=Weight of Sample, mg

1000000=Conversion Factor for ppm

$$\% \text{ Codeinone/14-hydroxycodeinone} = \text{ppm}/10,000$$

The results for Example 1 utilizing the procedure of Example 6 gave a result of <5 ppm of codeinone and 8 ppm of 14-hydroxycodeinone.

The results for Example 2 utilizing the procedure of Example 6 gave a result of <5 ppm of codeinone and <5 ppm of 14-hydroxycodeinone.

The results for Example 3 utilizing the procedure of Example 6 gave a result of <5 ppm of codeinone and 10 ppm of 14-hydroxycodeinone.

Many other variations of the present invention will be apparent to those skilled in the art and are meant to be within the scope of the claims appended hereto.

What is claimed is:

1. An oxycodone hydrochloride composition which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone.

2. The oxycodone hydrochloride composition of claim 1, having less than 15 ppm of 14-hydroxycodeinone.

3. The oxycodone hydrochloride composition of claim 1, having less than 10 ppm of 14-hydroxycodeinone.

4. The oxycodone hydrochloride composition of claim 1, having less than 5 ppm of 14-hydroxycodeinone.

5. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 0.25 ppm.

6. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 0.5 ppm.

7. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 1 ppm.

8. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 2 ppm.

9. The oxycodone hydrochloride composition of claim 1, wherein the composition has a lower limit of 14-hydroxycodeinone of 5 ppm.

10. A process for preparing an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone.

11. The process of claim 10, comprising combining hydrochloric acid and the oxycodone base composition in a solvent to form a solution, and isolating the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone from the solution.

12. The process of claim 10, wherein the oxycodone hydrochloride composition having less than 25 ppm 14-hydroxycodeinone is isolated from the solution by lyophilizing or spray drying the solution.